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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : DARTEY et al.
Serial No. : 09/461,887
Filed : December 15, 1999
Title : LONG CHAIN ALCOHOLS PROVIDED IN EDIBLE OILS

Art Unit : 1617
Examiner : Wang, S.

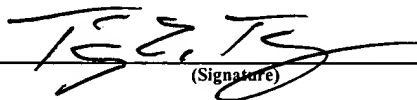
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Timothy E. Tracy

(Name of applicant, assignee, or Registered Representative)


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November 21, 2002

(Date of Signature)

Commissioner For Patents
Washington, DC 20231

SUBSTITUTE APPEAL BRIEF

Dear Sir:

In accordance with the provisions of 37 CFR § 1.191, a timely Notice of Appeal was filed in the captioned application on May 24, 2002 from the rejections made by the Examiner in the February 22, 2002 Office Action. This Substitute Appeal Brief is being submitted in response to the October 25, 2002 Office Communication wherein the Examiner stated that the original Appeal Brief was defective because the Attached Claims on Appeal do not present the actual claims on appeal. Three copies of the Appeal Brief are enclosed.

(1) Real Party in Interest

The real party in interest in the application in this appeal is Applicant's assignee McNeil-PPC, Inc., a corporation of New Jersey, a wholly owned subsidiary of Johnson & Johnson, a New Jersey corporation.

(2) Related Appeals and Interferences

No related appeals or interferences are known to exist.

(3) Status of the Claims

Claims 1-19 are the claims on appeal, a copy of which are attached hereto in the Appendix to this Brief. No claims stand allowed in this application.

(4) Status of Amendments

An amendment to the claims for purpose of this appeal is being submitted concurrently herewith under 37 CFR § 1.116. The last Amendment entered in this application was dated July 19, 2001.

(5) Summary of the Invention

The present invention is directed to composition and a process for preparing a comestible product containing long chain alcohols by providing a long chain alcohol; providing an edible oil containing less than about 12 weight percent linolenic acid that is substantially free of medium chain triglycerides composed of C₈ to C₁₀ fatty acids; and admixing the long chain alcohol in said edible oil to form a long chain alcohol/edible oil admixture that contains less than two weight percent high molecular weight alcohol, free of an emulsifier, and has a viscosity of less than 200 centipose measured at 70°F; and combining said admixture with other components of a comestible product.

(6) Issues on Appeal

Whether the inventions of claims 1-19 are unpatentable under 35 U.S.C. §103 as being obvious over Cain et al. (EP 0 901 804) ("Cain") in view of Kimura (CAPLUS abstract,

1994:321866) (“Kimura”), Hohnen Oil CO. (CAPLUS abstract, AN 1986:18914) (“Hohen”), and Tanaka (CAOLUS abstract, AN 1989:153130) (“Tanaka”)?

(7) Grouping of Claims

It is believed that all of the pending claims are patentable over the rejection made by the Examiner. For purposes of this Appeal, all of the claims stand together.

(8) Argument

(iv) Rejection under 35 USC § 103

Claims 1-19 were rejected as being unpatentable under 35 U.S.C. §103 as being obvious over Cain in view of Kimura, Hohen, and Tanaka.

For the reasons set forth below the rejection, respectfully is traversed.

In making the final rejection, the Examiner relied on the following reasoning set forth “in the prior office action.” (2/22/02 Office Action at 2.) In particular, the Examiner asserted that “Cain teaches a fat-containing product and the method of making the same.” (Paper No. 6 at 3.) The Examiner asserted that Cain’s mixture had reduced viscosity. The Examiner acknowledged, however, that Cain “does not expressly teach the employment of the particular vegetable oil or the particular food products herein, such as non-continuous oil phase products. (Paper No. 6 at 4.)

To fill the acknowledged gap, the Examiner relied upon Hohmen and Kimura as “teaching the employment of vegetable oil, such as soybean oil and corn oil for solubilization of fatty alcohols.” The Examiner also relied on Tanaka as “teaching employing oil-fatty alcohol mixture for making oil in water emulsion (non-continuous oil phase).” (Paper No. 10 at 3.)

The Examiner reasoned that:

(1) “[a] person of ordinary skill in the art would have been motivated to make an oil-long chain alcohol mixture wherein the oil is essentially free of medium chain triglyceride, or make the mixture into a non-continuous oil phase mixture because the long chain alcohol is known to reduce viscosity of oils, including those without medium chain glyceride,” (Paper No. 10 at 4);

(2) “[u]sing the alcohol-oil mixture taught by Cain to make a particular non-continuous oil phase food product is considered within the skill of the artisan, because it is known to employ oil-fatty alcohol mixture for making oil-in-water emulsion;”

(3) “optimization of the mixing procedure herein, is considered within the skill of the artisan;”

(4) “Cain’s claimed subject matter does not require any emulsifier or surfactant;”

(5) “Cain teaches the employment of long chain alcohol for reducing the viscosity of edible oil products;” and

(6) “[t]he difference claimed herein is in degree, not kind. Such variation is obvious and is well within the skill of the artisan.”

The Examiner concluded that “[I]t would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to make an oil-long chain alcohol mixture wherein the oil is essentially free of medium chain triglyceride, or make the mixture into non-continuous oil phase mixture.” (Paper No. 10 at 3.)

In response to the paper submitted on December 18, 2001 by the undersigned, the Examiner took the position that, inter alia, “the primary reference [sic] teaches that the employment of long change fatty alcohol would reduce the viscosity of fat-containing food product.” (2/22/02 Office Action at 3.) The Examiner further appeared to take notice that “soybean oil is a well-known edible oil.” Additionally, the Examiner contended that “the second reference further teaches that the particular long chain alcohol employed herein, octacosanol, are known to be employed with vegetable oil for health benefit.” The Examiner reasoned that “[t]he motivation to employ long chain alcohol in any-fat containing food product, including soybean oil and/or those defined herein, is very clear to one of ordinary skill in the art: a) reduce the viscosity of the food product, and b) provide health food.” The Examiner further asserted that “[t]he benefit of reducing the viscosity of food product should be well understood by one of ordinary skill in the art” citing Cain.

The Examiner also asserted that the viscosity differences were one degree, not in kind.

As is well settled, “[t]he examiner bears the burden of establishing a prima facie case of obviousness. . . . Only if this burden is met does the burden of coming forward with rebuttal argument or evidence shift to the applicant. . . . When the references cited by the examiner fail to establish a prima facie case of obviousness, the rejection is improper and will be overturned.” *In re Deuel*, 34 USPQ 2d 1210, 1214 (Fed. Cir. 1995).

Examiner Failed to Make a Prima Facie Case of Obviousness

1. **The Examiner has not made a proper record for why the references are combinable**

The mere fact that it is possible for isolated references disclosures to be combined does not render the result of the combination obvious absent a logical reason of record which justifies the combination. In *re Regal*, 188 USPQ 136 (CCPA 1975). To properly combine references to reach a conclusion of obviousness, there must be some teaching, suggestion or inference in the references or knowledge generally available to one of ordinary skill in the art, which would have led to combine the relevant teachings of the references. *Ashland Oil Inc. v. Delta Resins and Refractories, Inc.*, 5 USPQ2d 1532 (CAFC 1985).

A *prima facie* case of obviousness requires that the rejection describe with specificity why one skilled in the art would have combined references to arrive at the claimed invention. In the present case, no such explanation is found in the rejection.

Cain concerns preparing fat continuous dispersions for confectionery compositions. Kimura concerns the distribution of octacosanol in tissue and organs of mice after administration.

The Examiner has not provided the requisite specific motivation for one of ordinary skill in art to combine the cited documents. It is submitted that one of ordinary skill in the art would not combine Cain with Kimura. For this reason, the rejection is improper and should be withdrawn.

Similarly, there is no suggestion to combine Cain and Hohmen. Cain was concerned with preparing fat continuous dispersions for confectionery compositions. Hohmen was concerned with formulating a vitamin, emulsifier and octacosanol in a gelatin capsule. The Examiner has not provided the requisite specific motivation for one of ordinary skill in art to combine the cited

documents. It is submitted that one of ordinary skill in the art would not combine Cain with Hohmen. For this reason, the rejection is improper and should be withdrawn.

2. It appears that the Examiner Engaged in Hindsight Reconstruction

As the Examiner is aware by citing *In re Fine*, 837 F.2d 1071, 5 USPQ 2d 1596 (Fed. Cir. 1988) (February 22, 2002 Office Action at 2), binding precedent makes it clear that one "cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention."

Yet, it appears that the Examiner has done precisely what such case law cautions against doing. That is, pick and choose which parts of the references to rely to make the instant rejection. For example, the Examiner asserted that "Cain's claimed subject matter does not require any emulsifier or surfactant." (Paper No. 10 at 4.) However, Example IV at p. 4, ln. 36 of Cain affirmatively discloses the use of an emulsifier. Ignoring the complete disclosure of a cited document in favor of the "claimed subject matter" appears to be picking and choosing which parts of the cited document supports the particular conclusion the Examiner wishes to reach.

Additionally, Tanaka discloses preparing an emulsified beverage by solubilizing octacosanol by fats and oils, water-soluble emulsifiers, and oil soluble emulsifiers, then mixing with aqueous solutions. Yet, the Examiner wished to rely on Tanaka for "teach[ing] the usefulness of long chain alcohols in oil in water emulsion." (Paper No. 14 at. 2.) It appears that the Examiner has ignored the affirmative requirement of using an emulsifier in Tanaka's disclosure to make the document fit the conclusion the Examiner wished to make.

It is respectfully submitted that such practices are tantamount to hindsight reconstruction. For this additional reason, the rejection is improper and should be withdrawn.

3. Even if the Documents were combined, the Combination does not lead one to the Claimed Subject Matter

Amended independent claim 1, independent claim 12, and independent claim 17 each affirmatively require, among other things, that the claimed oil/alcohol admixture be free or substantially free of an emulsifier and have a viscosity of less than about 200 centipose (0.2 Pas)

at 70°F. As admitted by the Examiner, it appears that Cain does not disclose the requisite oil. Additionally, it appears that Cain does not also disclose the requisite viscosity of the claimed oil/alcohol admixture. Further, Cain discloses the use of an emulsifier.

As to the latter, Tanaka discloses preparing an emulsified beverage by solubilizing octacosanol by fats and oils, water-soluble emulsifiers, and oil soluble emulsifiers, then mixing with aqueous solutions. Kimura and Hohmen are silent with regard to the use of an emulsifier. Thus, when combined, it appears that the cited documents would lead one of ordinary skill in art to the conclusion that an emulsifier is required. However, the pending claims affirmatively require, among other things, that the admixture of the claimed invention be free or substantially free of an emulsifier. Therefore, it is respectfully submitted that the rejection is improper for this reason and it should be withdrawn.

As to viscosity, it appears that Cain took viscosity measurements at 50°C (122°F) and 70°C (158°F). The lowest viscosity measurement at 50°C (122°F) using octacosanol in Cain's disclosure was 0.28 Pas, which is not only at a temperature over 50 degrees higher than the claimed measurement temperature, but is also 40% greater viscosity at that higher temperature than that which is explicitly claimed. Further, at 70°C (158°C), which more than twice the claimed temperature for measuring viscosity, **Cain discloses** viscosities of 0.2025 and 0.1956 Pas. Such numbers were achieved by Cain using not only a greater temperature for measuring viscosity, but **adding, among other things, an emulsifier**. (See p.4, ln. 35 – p. 5, ln. 9.) In fact, the lower viscosity in Example IV of Cain was achieved when combining the emulsifier with long chain alcohol. (See p. 4, ln. 44.)

The secondary references relied upon by the Examiner do not close the gaps left by Cain because they are silent with regard to viscosity. For this additional reason, the rejection is improper and should be withdrawn.

Differences are in Kind, not in Degree

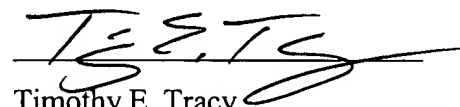
The Examiner asserted that the differences between the claimed subject matter and the cited documents are "in degree, not in kind." (Paper No. 10 at 4.) It is respectfully submitted that the

combination of documents relied upon by the Examiner in the instant claim would require the use of an emulsifier. However, the pending claims require, among other things, that the admixture be free or substantially free of an emulsifier. Because the combination differs structurally from the admixture of the pending claims, it is submitted that the difference is in kind, not in degree. For this additional reason, the rejection is improper and should be withdrawn.

Additionally, regarding the affirmative requirement of an emulsifier in Tanaka, the Examiner asserted that "[t]he employment of particular ingredients in a particular formula is a matter of optimization and is considered to be within the skill of the artisan." (Paper No. 14 at 2.) First, the standard for obviousness is "one of ordinary skill in the art," not the "skill of the artisan." Second, even if the Examiner had used the proper standard, there is no evidence in this record of an expectation of success if the admixture of the claimed invention was free or substantially free of an emulsifier given the affirmative requirement of Tanaka of an emulsifier. For these additional reasons, the rejection is improper and should be withdrawn.

Accordingly, for the reasons set forth above, withdrawal of the rejections and allowance of the claims is respectfully requested.

Respectfully submitted,



Timothy E. Tracy
Reg. No. 39,401
Attorney for Applicants
Filed under 37 CFR §1.34(a)

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-6586
November 21, 2002

APPENDIX

(9) Claims on Appeal

1. A process for preparing a comestible product containing long chain alcohols comprising:
providing a long chain alcohol; providing an edible oil containing less than about 12 weight percent linolenic acid that is substantially free of medium chain triglycerides composed of C₈ to C₁₀ fatty acids;
admixing said long chain alcohol in said edible oil to form a long chain alcohol/edible oil admixture that contains less than two weight percent high molecular weight alcohol, free of an emulsifier, and has a viscosity of less than 200 centipose measured at 70°F; and
combining said admixture with other components of a comestible product.
2. The process of claim 1 wherein the long chain alcohol is policosanol.
3. The process of claim 1 wherein the long chain alcohol is octacosanol.
4. The process of claim 1 wherein the edible oil is a vegetable oil.
5. The process of claim 1 wherein the comestible product is a non-continuous oil phase product.
6. The process of claim 5 wherein the non-continuous oil phase product is a margarine.
7. The process of claim 5 wherein the non-continuous oil phase product is a spread.
8. The process of claim 5 wherein the non-continuous oil phase product is a salad dressing.
9. The process of claim 4 wherein the non-continuous oil phase product is a mayonnaise.
10. The process of claim 1 wherein the amount of the long chain alcohol admixed in the edible oil comprises from about 0.0001% to about 0.4 weight % of the comestible product.
11. The process of claim 1 wherein the amount of the long chain alcohol admixed in the edible oil comprises from about 0.001% to about 0.01% of the comestible product.
12. Method for preparing a long chain alcohol in an edible oil material comprising:
providing an edible oil substantially free of medium chain triglycerides composed of C₈-C₁₀ triglycerides and containing less than about 10 weight percent linolenic acid;
providing a long chain alcohol;

admixing said edible oil and long chain alcohol in the presence of an energy source such that the long chain alcohol is admixed in the oil; said long chain alcohol/edible oil admixture is stable and free of an emulsifier or surfactant; and having a viscosity of less than about 200 centipoise as measured at 70 °F.

13. The method of claim 10 wherein the long chain alcohol and oil are heated to a temperature

of from about 160 to about 180 °F.

14. The method of claim 11 wherein the long chain alcohol is provided at a level of from about 0.1 to about 2 weight percent based upon the level of the oil.

15. The method of claim 12 wherein the long chain alcohol is policosanol.

16. The method of claim 13 wherein the policosanol has an octacosanol content of greater than about 65 weight percent.

17. A composition comprising :

a stable edible oil /long chain alcohol admixture substantially free of an emulsifying or surfactant agent, the edible oil substantially free of medium chain triglycerides composed of C₈-C₁₀ triglycerides and containing less than about 10 weight percent linolenic acid;

the admixture having a viscosity of less than about 200 centipoise as measured at 70 °F.

18. The composition of claim 17 wherein the long chain alcohol is from about 0.1 to about 2 weight percent of the total composition weight.

19. The composition of claim 18 wherein the long chain alcohol is policosanol.